

REMARKS

Claims 14-39 are pending in this application.

Claims 36-39 have been canceled.

Claims 29 and 30 have been amended. Support for claim amendments is found in the claims as originally filed and throughout the specification. For example, support for amending Claim 29 is found in previously presented Claims 1, 14, 23, and 29. Support for amending Claim 30 to include the terms "colorectal carcinoma" is found on page 12, lines 2-7 or in Example 4D, and the terms "ovarian carcinoma" is found in Example 4A.

Claims 40-44 have been added. Support for amending Claims 40-42 can be found in previously presented Claims 15-17. Support for amending Claim 43 is found on page 4, lines 31-33 of the specification. Support for amending Claim 44 is found in previously presented Claim 27.

No new matter has been added.

RESTRICTION REQUIREMENT

The Official Action distinguishes between Claims 14-28 directed to an *in vitro* method of making CAPRI cells ("Group I"), and Claims 29-39 directed to an *in vivo* method of treating cancer ("Group II").

Applicant traverses and submits that these methods are not completely independent in that the claimed *in vivo* method for treating cancer (Claims 29-39) utilizes the CAPRI cells produced by the *in vitro* methods recited in Claims 14-28. According to the Official Action, because " 'CAPRI cells' can be made by a materially different process, for example, by producing the activated antigen presenting cells of

the first step of claim 14 not as claimed by rather by transfecting tumor cells obtained from a first biopsy ... with genes that activate T cells, such as an expression construct that produces a membrane bound anti-CD3 antibody" (emphasis added), the Examiner believes that the claimed methods categorized as Group I and Group II are patentably distinct. Applicant notes that independent Claim 29, as previously presented, was provided in dependent form and recited "A method for treating cancer, the method comprising: administering the CAPRI cells of Claim 14 into a cancer patient" (emphasis added). Applicant intended to recite CAPRI cells produced by the method of Claim 14. Alternatively, independent Claim 29 has been amended to incorporate relevant steps recited in independent Claim 14 to indicate that these steps are included in the *in vivo* methods for treating cancer, as recited in Claims 29-44, as currently presented. Thus, Applicant requests the withdrawal of the restriction requirement for election of invention.

However, to comply with the Restriction Requirement of this Official Action, Applicant elects Group II, drawn to methods for treating cancer with CAPRI cells as recited in Claims 29-44, as currently presented.

REQUIREMENT FOR SPECIES SELECTION

If Applicant elects Group II for prosecution on the merits, the Official Action further requires multiple species elections as set forth on pages 7-8.

With respect to Claim 30, Applicant is required to elect one specific cancer to be treated (**item 10**, Official Action), either melanoma or breast carcinoma or bowenoid papilloma. The Official action alleges that these pathological conditions are patentably distinct because "they differ in etiologies and therapeutic endpoints."

Applicant traverses and submits that the present invention directed to a method for treating cancer, as recited in independent Claim 29, is a generic method applicable to more than one specific type of cancer/disease. By definition, cancer arises from a population of cells of an individual exhibiting uncontrolled growth rate. The particular cell population (or cellular tissue) affected by cancer can vary depending on which cellular type (of a tissue/organ) incurs the carcinogenic mutagen. Applicant submits that the methods of Claims 29-44 of the present invention are applicable to the treatment of various types of cancer, and are independent of specific tissues/organs affected. Furthermore, because cancers, by their general nature, that develop in one tissue/organ often metastasize to other and multiple tissue/organ sites within the affected individual (e.g., see specification, at page 17, last paragraph), cancers of any type are amenable to treatment by the methods of Claims 29-44. Thus, requiring the Applicant to elect a particular cancer species affecting only one particular tissue/organ is not reasonable when one considers the generic concept of the invention (which can be applied to any type of cancer) and the fact that various types of cancers develop simultaneously/contemporaneously within the same cancer-afflicted individual. Such a requirement is not appropriate for the claimed method because treatment of various types of cancers that can develop by metastases would not be captured by introducing such a limitation into the present method claims. Thus, Applicant requests the withdrawal of the requirement for the species election.

However, to comply with the procedural requirements, Applicant provisionally elects, *with traverse*, and for the purpose of searching only, breast carcinoma. In addition, Applicant notes that the various carcinomas recited in Claim 30 are

presented as a Markush-type claim, the examination which should be extended to include other species if the Examiner determines that the elected species is allowable under MPEP § 803.02.

With respect to the election of Group II, Applicant is further required to elect whether the administration of CAPRI cells does or does not further comprise administration of CD-3 activated T cells to a patient (**item 11**, Official Action).

Applicant traverses and submits that requiring Applicant to make such an election is unreasonable in that, in general, cancer treatments, such as the claimed methods of Claims 29-44, often involve combination therapy, which may include the administration of CAPRI cells and the additional administration of CD-3 activated T-cells to a patient. Thus, Applicant requests the withdrawal of the requirement for the species election.

However, Applicant provisionally elects, *with traverse*, and for the purpose of searching only, the method for treating cancer without the administration of CD-3 activated T cells to a patient.

Applicant expressly reserves the right to traverse any subsequent divisions made by the Examiner of the present invention into “inventive groups” following the present provisional species election for examination. Applicant has no intention of abandoning any non-elected subject matter, and should it be necessary, Applicant expressly reserves the right to file one or more continuation and/or divisional applications directed to non-elected subject matter.

With regard to the required species elections, the Applicant submits that the M.P.E.P. § 803 provides: “If the search and examination of an entire application can

be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions.” In addition to showing the serious burden, the Patent Office is also under an obligation to demonstrate that the species are independent and/or distinct. M.P.E.P. § 806.04(b). The Applicant further submits that a reasonable number of species may still be claimed in one application under 37 C.F.R. § 1.141 and M.P.E.P. § 806.04(a). The Office Action fails to provide any basis for finding the various members of the generic classes in question as independent and/or distinct. Because the Office Action fails to set forth any distinction among the purported species and fails to explain why the amount of purported species would be seriously burdensome on the Examiner, the Applicant respectfully requests the reconsideration and the withdrawal of the multiple species election requirement.

CONCLUSION

Based on the current amendments and arguments presented, the withdrawal of the requirement for election of species is requested. Further and favorable consideration of the claims based on the merits is respectfully requested.

Should the Examiner have any questions concerning this Response, or the subject application in general, a telephone call to the undersigned attorney would be greatly appreciated so that the prosecution of this application may be expedited.

Respectfully submitted,

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